Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1, phrase "the second lens selectively positionable with the distal end of the shaft in the second position" (lines 16-17) is confusing since the second lens is recited as being coupled to the catheter (as opposed to the "shaft" of line 2). It appears that the word "shaft" should more properly be --catheter--.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 3, 10, 12, 13, 43, 44, 54-57, 61-63, 66-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaiya (U.S. Pat. 5,178,130) in view of Torii (U.S. Pat. 6,482,149).

As to claims 1, 54 and 55, Kaiya discloses a shaft/endoscope (6a, Fig.2) extending along a longitudinal axis and having distal and proximal ends (13a,15a, Fig.2) and defining a hollow channel therethrough (16); a first image lens (28a, Fig.1) selectively positioned adjacent to the distal end of the insertion tube for receiving a first image in a first direction, the first direction being a generally forward circumferential view that is parallel to the longitudinal axis of the shaft

(note Fig.1); a catheter (endoscope 2b) receivable in the hollow channel of the shaft for extension and retraction relative to the distal end of the shaft (note Fig.2, col.3, lines 46-54), the catheter including a distal end (13b), proximal section (15b) and a bending section (14b) interposed between the distal and proximal ends; and a second image lens/rear view module (28b, Fig.1) coupled to the distal end of the catheter (Fig.1), the second image lens selectively positionable with the distal end of the catheter in a second direction with respect to the first image lens when extending beyond the first lens so as to receive a second image in the second direction. Kaiya teaches that the shaft (6a) and catheter (2b) comprises curvable sections (14 a,14b, col.3, lines 40-45), as opposed to merely a flexible section (15a,15b). The Examiner takes the position that this 'curvable section' anticipates a steering/actuation mechanism which will actively allow curving in a desired direction and thus allow the second direction to be at a predetermined angle to the first direction. Furthermore, insertion of the distal end (13b) of the catheter (2b) through and out of channel (16) anticipates the second lens having the capability of being selectively independently advanced generally parallel to the longitudinal axis relative to the first lens.

Clearly, both the shaft and catheter of Kaiya are capable of being flexed but since Kaiya fails to provide any particulars as to the curvable sections of the endoscope/catheter, the angle to which they can be flexed is not ascertainable. Torii is one of many references which evidences what is known in the endoscope art. Torii teaches an actuator mechanism for bending the curving section (22, Fig.1) of an endoscope in four perpendicular directions comprising at least first and second wires (54, Fig.2, col.9, lines 23-25). The curving section can be bent well over 180 degrees from the longitudinal axis (Fig.19). Given the lack of disclosure as to the particulars of the curvable section in Kaiya, it would have been obvious to one of ordinary skill in this art to

have turned to the prior art to "fill in the gaps" when reducing the Kaiya device to practice. Indeed, use of the known curvable section as taught by Torii for the curvable section of Kaiya would have been part of the ordinary capabilities of a person skilled in this art. Use of such known curvable part would allow the angle between the first direction and second direction to be at least 180 degrees, increasing the view capability and providing the catheter (2b) the ability to be directed at a target that would not be accessible to the shaft (6a).

As to claim 3, since the first and second lenses are used simultaneously (Fig.2), they inherently receive images simultaneously.

As to claims 10 and 56, and as mentioned above, the Examiner takes the position that, in order to be 'curvable', each of the endoscope and catheter shafts must inherently have some kind of active mechanism to provide the curvable function. This mechanism would anticipate an 'actuator' as broadly as claimed. However, the teachings of Torii also teach an actuator whose wires extend to the distal end of the catheter.

As to claims 12 and 61, note imaging device (29b) and processor (32b) in Figure 1.

As to claims 13 and 62, display screens (5a,5b) constitute a display screen for displaying the first and second images. Also note col.9, line 66 to col.10, lines 4.

As to claim 43 and 57, the curvable section/actuator taught by Torii include first and second wires (54, Fig.2), the distal ends of which, alone or in combination with the inner structure that is bent (e.g., links 40, Torii), constitute bending structure.

As to claim 63, Kaiya teach that the both endoscopes (2a,2b) can be fiberscopes with externally fitted camera (col.9, lines 61-65). As evidenced by Karasawa et al. (U.S. Pat.

5,196,928), a fiberscope with external camera (2b, Fig.5 of Karasawa et al.) includes an eyepiece (9d, Fig.5, col.5, line 63 to col.6, line 24).

As to claims 44, 66 and 67, the wires (54) of Torii would anticipate a "bending structure disposed at the distal end of the catheter" that "urges the catheter into the second direction upon exit from the hollow channel".

As to claim 68, the wires (54) taught by Torii anticipate "cables".

As to claims 69 and 70, the diameter of catheter (2b) can constitute a maximum outer dimension, even when measured perpendicular to the axis and when the catheter is bent. Such dimension is inherently less than the outer diameter of the shaft.

As to claims 71 and 72, as set forth above, the first and second lenses are capable of providing different views (e.g., forward, rearward) due to the capability of the catheter to be flexed. Since there is no indication that imaging can not occur during movement (e.g., insertion) of the endoscope/catheter of Kaiya and it would not be reasonable to doubt that it could occur, then the Kaiya reference is capable of imaging during movement.

As to claims 73 and 74, since the catheter would be capable of up to 180 degrees of bending, the combination is capable of viewing two different tissues (even a 90 degree of the catheter could accomplish this).

5. Claims 15, 16, 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaiya in view of Torii and further in view of Yoon (6,066,090).

Kaiya in view of Torii disclose the device as described above and that the illumination for both the endoscopes (2a,2b) is provided by an optical fiber waveguide (17a,17b). Thus,

Kaiya fails to disclose one or more illumination bulbs disposed on the distal tip of the catheter. Yoon et al. discloses a similar endoscope system in which either of the endoscopes (14, 16 or 18) can include an optical wave guide for illumination but alternatively can include LEDs or incandescent bulbs located at the distal end (col.5, lines 1-12). Since both Kaiya and Yoon teach endoscope devices and illumination sources, it would have been obvious to one of ordinary skill in the art to have substituted one alternative illumination arrangement for another to achieve the predictable result of providing illumination to the field of view. One would be motivated to use an illumination bulb (e.g., LED) at the distal end to eliminate the need optical fibers to extend through the shaft, which fibers attenuate light and are capable of breaking.

Inherently, use of any electrical bulb source (i.e., LED) will require a connection to a power source.

6. Claims 1, 3, 10, 12, 13, 15, 16, 43, 44, 54-57, 61, 62, 64-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (U.S. Pat. 6,066,090).

Yoon discloses a shaft/endoscope (12,14, Fig.1) extending along a longitudinal axis (e.g., z-axis in Fig.4) having a distal end (14) and a proximal end (12) comprising a first lens (36, Fig.2) fixedly attached at the distal end which can receive a first image of a forward direction (in the condition that it is not bent, note 44 Fig. 8 for example, it would be along the longitudinal axis) and a catheter (18, Figs.1,2) including a distal end (24), a proximal end (25) and a bending section (see below) and further including a rear view module/second lens (36 on 18) for simultaneously receiving a second image at a predetermined angle to the first direction (in the condition that it is bent, note 46 in Figure 4 for example). The catheter (18) is receivable in a

hollow channel (note channel of shaft 12 that accommodates 18, Fig.1). The distal end of the shaft (14) and the catheter (18) are independently steerable via an actuator up to approximately 180 degrees (note col.5, line 51 to col.6, line 34, which incorporates Shockey, U.S. Pat.5,168,864 and Hibino et al., U.S. Pat. 4,982,725, by reference as showing a suitable steering control mechanisms; note col.2, lines 20-30 of Shockey which teaches 180 degree deflection; and Figure 1, elements 10 and 13 of Hibino et al., col.8, lines 4-22 which show multiple control wires and bending in four perpendicular directions). Any of the steering mechanisms disclosed or incorporated by reference by Yoon would anticipate a “bending structure disposed at the distal end of the catheter” that “urges the catheter into the second direction upon exit from the hollow channel". Note that all lenses operatively connect to an image processor (26) and monitor (27) (Fig.1). The rear view module can include a LED (54b) which is a “bulb” and requires a power source. Steering up to 180 degrees (mentioned above) would conceivably allow for different images to be simultaneously obtained. There is no reason to believe that the Yoon device is not capable of producing images during movement of the entire device or any one or more of the branches. The diameter of branch (18) can constitute a maximum outer dimension, even when measured perpendicular to the axis and when the catheter is bent. Such dimension is inherently less than the outer diameter of the shaft (12).

It would appear that, due to the fact that each endoscope branch (14, 16 and 18, Fig.1) is individually and separately steered and individually rotatable about their respective longitudinal axes (col.4, lines 27-37), and the fact that no structure is disclosed that secures the branches in any particular manner to the shaft (12, Fig.1), that each endoscope branch would be capable of extension and retraction with respect to the shaft (12). However, Yoon fails to explicitly

mention such capability. If not inherently contemplated by Yoon, it would have been obvious to one of ordinary skill in the art to have allowed the endoscope branches (14,16,18, Fig.1) to also be capable being moving in the direction of the longitudinal axis, and more advantageously, independently movable in that direction. This would provide an extra degree of freedom to the independently steerable and rotatable branches, thus making each branch easier to maneuver as desired. Therefore, this would anticipate the limitation of the catheter being reversibly received within the channel of the shaft or receivable in the shaft for independent extension or retraction generally parallel to the axis of the shaft.

Response to Arguments

7. Applicant's arguments filed July 7, 2009 have been fully considered but they are not persuasive.

Regarding the Kaiya reference, it must be pointed out that Kaiya explicitly teaches a 'curvable' section for each endoscope, inherently providing the capability of the endoscope (2b) to be flexed so as to provide a different (second) field of view in a different direction. The only feature that Kaiya does not explicitly teach, with respect to claims 1 and 54, is how far the endoscope (2b) can be bent. However, an angle of up to 180 degrees is not uncommon in the endoscope art and Torii evidences that such is possible and has been contemplated.

Regarding Applicants arguments, Applicant argues that Kaiya teaches away from allowing the endoscope (2b) to bend up to 180 degrees and that giving it this capability would "make the device of Kaiya wholly unsuitable for its intended purpose". The Examiner respectfully disagrees.

Initially, it is noted that Applicant bases his arguments on the assumption that the system of Kaiya can ***only*** provide images from each endoscope when they are viewing the **same** tissue from the **same** direction. There is no indication or evidence whatsoever in Kaiya that this assumption is correct. In fact, each endoscope (2a,2b) of Kaiya are in and of themselves fully functioning endoscopes that independently and simultaneously obtain images of each respective field of view (col.5, lines 12-38). The only difference being that the imaging cycle (e.g., including illumination periods) of each endoscope are synchronized with each other so that, when the situation arises where illumination light from one endoscope could be sensed by the other endoscope, the illumination periods of each endoscope do not interfere with the imaging cycle of the other respective endoscope. The situation mentioned above **could** occur when the illumination light of both endoscopes are directed at the same tissue but can equally occur from mere reflection of light from different tissue, such as with the case where one endoscope is illuminating and viewing tissue in a different direction.

The fact of the matter is, even if the endoscopes (2a,2b) of Kaiya are imaging totally different, oppositely directed view fields, each endoscope will still function to generate an image. There is no evidence in Kaiya, or presented by Applicant, that in such a case the endoscopes would just stop working. Thus, modification to allow the endoscope (2b) of Kaiya to bend up to 180 degrees, as opposed to bending to an angle of less then 180 degrees (which is supported by Kaiya as mentioned above), would not make the Kaiya system unsuitable for its intended purpose but only enhance its capabilities and functionality. Therefore, the rejection over Kaiya in view of Torii has been maintained.

Regarding the Yoon reference, Applicant argues that the endoscopes of Yoon are taught to be advanced simultaneously and not independently. This has been recognized by the Examiner and is the basis for the obviousness rejection under 35 USC 103(a). The endoscope branches are already taught by Yoon to be independently bendable and independently rotatable (note rejection), so modification to allow for independent axial movement within shaft (12) would not make the device "unsuitable for the intended purpose" but instead would enhance its capabilities by allowing another degree of freedom of movement when positioning the distal ends. Furthermore, providing independent axial movement between the endoscopes of Yoon would not eliminate the capability of the endoscopes being simultaneously advanced since they are all contained in a common housing (12) that would allow for that. It is the Examiner's position that modification of Yoon as set forth in the rejection above would not make the modified device wholly unsuitable for the intended purpose of Yoon. Therefore, this rejection has been maintained.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Leubecker whose telephone number is (571) 272-4769. The examiner can normally be reached on Monday through Friday, 6:00 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John P. Leubecker/
Primary Examiner
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jpl